

Claims amended

Claims 1 to 8 are amended. Pending claims *after* entry of the instant amendment is attached as Appendix A.

No teaching or suggestion in the prior art

Applicant thanks the Examiner for determining that there is no teaching or suggestion in the prior art to use the SKG mouse in the methods of breeding to produce progeny which display symptoms associated with rheumatoid arthritis and that claims would be allowable if the section 112 issues are resolved.

Outstanding Rejections

Claims 1 to 11 stand rejected under 35 U.S.C. §101 and 35 U.S.C. §112, first paragraph. Applicants respectfully traverse all outstanding objections to the specification and rejections of the claims.

Support for the Claim Amendments

The specification sets forth an extensive description of the invention in the amended claims. Support for amended claims directed to the inbred mouse strain of the invention, methods for making these mice, and screening methods using these mice, can be found, *inter alia*, on page 2, lines 19 to 26; and, in Example 1, pages 4 to 9.

The Title

Applicant believes the new title as set forth in the instant amendment is clearly indicative of the invention to which the pending claims are directed.

The Telephonic Interviews

Applicant thanks the Examiner for the courteous and helpful interviews. A declaration by the inventor addressing the issues raised in the interviews is enclosed herein.

Issues under 35 U.S.C. §101

Claims 1 to 11 stand rejected under 35 U.S.C. §101, as allegedly directed to non-statutory subject matter. In particular, it is alleged that the claims are drawn to an SKG mouse which has not been altered by the hand of man and is a naturally occurring animal.

Applicant's reference U.S. Patent No. 6,040,495, for the proposition that the United States Patent and Trademark Office is not adverse to allowing claims directed to inbred mouse strains that were developed by selection and specific breeding over multiple generations (see Applicant's response submitted May 12, 2000).

Applicant respectfully avers that the inbred mouse strain of the instant invention was similarly developed by selection and specific breeding over multiple generations. Attached herein is a declaration under 37 CFR §1.132 by the inventor, Dr. Shimon Sakaguchi, that specifically sets forth how the hand of man was necessary to develop the new inbred mouse strain of the claimed invention. As declared by Dr. Sakaguchi, without the inventive identification of the mutation by the inventor, and without the hand of man, the claimed inbred strain could not have been developed. Dr. Sakaguchi notes that he selected a specific breeding strategy (as discussed in the specification and the declaration) to detect recessive mutations. Accordingly, the rejection under section 101 can be properly withdrawn.

Issues under 35 U.S.C. §112, first paragraph

Claims 1 to 11 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains to make and/or use the invention. It is specifically alleged that the specification does not reasonably provide enablement for an SKG mouse strain that develops onset of autoimmune arthritis.

The Patent Office does states that the specification is enabling for an SKG mouse strain that develops natural onset rheumatoid arthritis and methods of producing and using this mouse strain.

As discussed in the telephonic interviews, to address this issue, Applicant will deposit embryos from the claimed mouse strain in a Budapest Treaty-authorized depository at the time the Patent Office determines that pending claims are allowable. Accordingly, the rejection under 35 U.S.C. §112, first paragraph, can be properly withdrawn.

CONCLUSION

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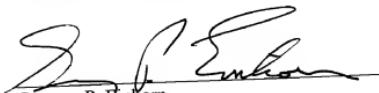
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In view of the foregoing remarks, it is believed that the Examiner should withdraw the rejection of the pending claims under 35 U.S.C. §112, first paragraph and 35 U.S.C. §101. Applicants believe all claims pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at (858) 678-5070.

Respectfully submitted,

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